REMARKS

Reconsideration of this Application is respectfully requested. Claims 36, and 43-50 are pending. Claims 36 and 43-50 are currently amended. New Claims 51 and 52 have been added. No new matter is added. Applicants respectfully request reconsideration of the rejections and entry of the amendment is respectfully requested.

In the Office Action of December 16, 2004, the Examiner set forth a number of grounds for rejection. These grounds are addressed individually and in detail below.

Claims 36, 43, 44, 46 and 47 stand rejected under 35 U.S.C. § 112, first paragraph, as lacking written description on the basis that they are genus claims which encompass any CEA transcriptional regulatory element (TRE) from any animal. Applicants respectfully disagree with the basis for this rejection however, as amended the claims recite "human" CEA TREs that "consist essentially of" the recited sequences.

Claims 43-50 stand rejected under 35 U.S.C. § 112, second paragraph, as lacking antecedent basis for "said CEA enhancer" and "said CEA promoter". The claims have been amended to recite "said CEA TRE".

Claims 48-50 stand rejected under 35 U.S.C. § 112, second paragraph, as indefinite. The claims have been amended to recite "SEQ ID NO:1" without reference to nucleotide number. In view of the above amendments and remarks, withdrawal of the rejections under 35 U.S.C. § 112 second paragraph is requested.

Claims 36 and 43-50 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Hallenbeck et al. (WO96/17053) in view of Richards et al. (WO 95/14100). Applicants respectfully submit that the presently claimed invention is not obvious in light of combination of the cited references.

As previously argued, the disclosure in Hallenbeck et al. (WO 96/17053) provides a description of adenoviral vectors that contain a gene which is essential for replication, operably linked to a heterologous transcriptional regulatory sequence (TRE), such that replication is conditioned on the presence of a trans-acting transcriptional regulatory factor. As the Examiner has acknowledged, while Hallenbeck et al. recite a variety of transcriptional regulatory sequences, the reference does not disclose the particular CEA regulatory sequences recited in the current claims. Hallenbeck et al. do not provide one of skill in the art with guidance useful to isolate the claimed CEA TRE sequences.

The Examiner relies on Richards et al. (WO95/14100) to compensate for the deficiencies in Hallenbeck et al. (WO 96/17053), arguing that Richards et al. disclose that "genes of interest will be expressed in CEA producing cells when the CEA enhancer sequences, disclosed therein, are present" and that "Richards teaches the use of the disclosed CEA regulatory regions in virions, for selective cytolysis of target cells." In making this rejection, the Examiner has identified a key difference between the Richards et al. disclosure and the currently claimed invention. The Examiner's statement in the first paragraph of page 7 of the Office Action captures the difference, wherein the Examiner cites to page 4 of Richards et al. as stating that "[T]his [cell cytotoxicity] is achieved by the construction of a molecular chimera comprising a "target tissue-specific" TRS that is selectively activated in target cells, such as cancerous cells, and that controls the expression of a heterologous enzyme." The Examiner relies on this statement for the proposition that the general concept of selective expression of cytotoxic compounds in target cells using the disclosed enhancer and promoter sequences from the human CEA gene are taught by Richards et al.

Applicants agree with the Examiner that Richards et al. teaches the use of transcriptional regulatory sequences (TRSs) for targeted gene therapy. In other words Richards et al. discloses that the TRS controls expression of a gene (i.e. a "heterologous enzyme") that is cytotoxic to tumor cells, for example, cytosine deaminase together with 5-FC (page 5, lines 7-19; page 8, lines 9-14 and page 15, line 31- page 17, line 15). However, Richards et al. do not describe or suggest the use of a TRE to control expression of adenoviral genes such that the adenovirus can replicate resulting in selective cytolysis of a target cell due to adenoviral replication, as presently claimed. The claimed invention does not rely on the CEA TRE (TRS) to effect expression of a "heterologous enzyme" or other gene that is cytotoxic (as disclosed by Richards et al.)

In view of the above remarks, Applicants respectfully submit that the presently claimed invention is not anticipated or made obvious by the cited references. Withdrawal of the rejections is requested.

CONCLUSION

In light of the above, Applicants submit that this application is now in condition for allowance and therefore request favorable consideration. If any issues remain which the Examiner feels may be best resolved through a personal or telephonic interview, the

Examiner is respectfully requested to contact Applicants' counsel, Linda R. Judge at (415) 836-2586.

Respectfully submitted,

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